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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/764,212

Applicant(s)

SIMALA-GRANT ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 24-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 28-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,25,27 and 45-47 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-7, 24-47 are pending. Claims 24-27 (amended) and 45-47(new) are under consideration.

Allowable Subject Matter

1. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, excluding the claim limitations that are rejected under 35 USC 112, first paragraph, and including all of the limitations of the base claim and any intervening claims.

Prior Art Rejections Withdrawn

1. Claims 24, 25 and 27 rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (2000) is herein withdrawn in light of the fact that Wang et al do not disclose an amino acid sequence, though the fucosyltransferase of UA1111 was utilized in isolated form in an in vitro assay (see page 1192, col. 1, paragraph 2, second half of paragraph).
2. Claims 24 and 27 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9 of copending Application No. (Taylor and Ge, PG-Pub 2002/0068347, publication date June 6, 2002) is herein withdrawn in light of the fact that the Applicant issued as Patent 6,534,298, and claims polynucleotides and not proteins in the issued claims.

Rejections Maintained/Response to Arguments

2. Applicant's arguments filed November 14, 2006 have been fully considered but they are not persuasive.
3. ***Rejection Maintain, Claim Rejections - 35 USC § 102*** The rejection of claims 24-25, and 27 under 35 U.S.C. 102(e) as being anticipated by Taylor and Ge (US Pat. 6,962,806, filing date July 3, 2002) is traversed on the grounds that the "'806 patent does not disclose or suggest an isolated polypeptide having at least 90% amino acid sequence identity to the full-length of SEQ ID NO 16.

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4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., to the full length of SEQ ID NO) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's claim recites "to the full length of an amino acid sequence of SEQ ID NO 16" and not as recited in Applicant's Remarks: "to the full length of SEQ ID NO 16". Applicant's traversal is not commensurate in scope with the instantly claimed invention as now claimed. Amendment of the claim to recite the phrase used to traverse the application of this reference against the claims could obviate the rejection.

3. The rejection of claims 24 and 27 under 35 U.S.C. 102(b or e) as being anticipated by Taylor and Ge (PG-Pub 2002/0164749, publication date November 7, 2002) is traversed on the grounds that the '749 patent does not disclose or suggest an isolated polypeptide having at least 90% amino acid sequence identity to the full-length of SEQ ID NO 16.

4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., to the full length of SEQ ID NO) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's claim recites "to the full length of an amino acid sequence of SEQ ID NO 16" and not as recited in Applicant's Remarks: "to the full length of SEQ ID NO 16". Applicant's traversal is not

commensurate in scope with the instantly claimed invention as now claimed. Amendment of the claim to recite the phrase used to traverse the application of this reference against the claims could obviate the rejection.

5. The rejection of claims 24, 25 and 27 under 35 U.S.C. 102(b) as being anticipated by Rasko et al (2000) is traversed on the grounds that Rasko et al does not disclose or suggest an isolated polypeptide having at least 90% amino acid sequence identity to the full-length of SEQ ID NO 16.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., to the full length of SEQ ID NO) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's claim recites "to the full length of an amino acid sequence of SEQ ID NO 16" and not as recited in Applicant's Remarks: "to the full length of SEQ ID NO 16". Applicant's traversal is not commensurate in scope with the instantly claimed invention as now claimed. Amendment of the claim to recite the phrase used to traverse the application of this reference against the claims could obviate the rejection.

7. **Maintained, Double Patenting** Claims 24, 25, 27 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No.6,962,806 is traversed on the grounds that the "806 patent does not disclose or suggest an

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isolated polypeptide having at least 90% amino acid sequence identity to the full-length of SEQ ID NO 16.

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., to the full length of SEQ ID NO) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's claim recites "to the full length of an amino acid sequence of SEQ ID NO 16" and not as recited in Applicant's Remarks: "to the full length of SEQ ID NO 16". Applicant's traversal is not commensurate in scope with the instantly claimed invention as now claimed. Amendment of the claim to recite the phrase used to traverse the application of this reference against the claims could obviate the rejection.

9. The rejection of claims 24 and 27(provisionally) on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9 of copending Application No. (Taylor and Ge, PG-Pub 2002/0164749, publication date November 7, 2002) is herein maintained in light of an effective terminal disclaimer was not submitted.

New Grounds of Objection/Rejection

10. Claims 24-25, 27 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

First, it is evident from the specification that applicant is describing their novel "Helicobacter pylori FutB " polypeptide specifically by a novel reference sequence (SEQ ID NO:16) .

The claimed genus of "fucosyltransferase protein" comprise an amino acid sequence of SEQ ID NO 16 and must evidence fucosyltransferase activity. The specification also broadly describes their novel "fucosyltransferase protein" to include polypeptides that include amino acid changes (see for example page 18 [0076] and page 9, [0045]) . Applicant broadly describes the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of amino acids found in the reference sequence (see page 18, [0076] and page 9, [0045] "polymorphic variants, alleles, mutants and interspecies homologs").

The Specification does not describe a representative number of species within the instantly claimed highly variable genus of fucosyltransferases that comprise an amino acid sequence of SEQ ID NO 16, with additional amino acids from another source and still have the ability to catalyze the transfer of a fucose residue from a donor substrate to an acceptor substrate and evidence the claimed biological function.

The Specification teaches the importance of the catalytic domain of the polypeptide (see [0046], page 10), but none of the claimed fucosyltransferase proteins are required to comprise the critical catalytic domain of SEQ ID NO 16, merely "an amino acid sequence". What the catalytic domain sequence is that provides the claimed genus with the fucosyltransferase activity is not specifically claimed, and the instant Specification only shows a single catalytic domain held in

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common with other fucosyltransferases, from other sources and does not include the catalytic domain of SEQ ID NO 16.

Claims 24-25 and 27 only require the claimed fucosyltransferase to comprise “an amino acid sequence of SEQ ID NO 16” and claims 45-47 only require “an amino acid sequence of SEQ ID NO 16” which is incorporated into a polypeptide of 100 or 200 amino acids, which is further combined with additional amino acids to produce a fucosyltransferase protein.

The “fucosyltransferase protein” of claims 45-47 comprise polypeptides that evidence sequences that have a recited degree of change as compared to a region of 100 or 200 amino acids, and this region need only comprise “an amino acid” subsequence of SEQ ID NO:16; the “fucosyltransferase protein” corresponds to sequences from other bacterial species, mutated sequences, allelic variants (see Instant Specification, page 9, [0045]). The claims encompass polypeptide sequences *comprising* portions of SEQ ID NO:16, SEQ ID NO 16 having more than 400 amino acids in the protein, but what the source or sequence of the claimed genus of “fucosyltransferase protein” that only comprises a subsequence of SEQ ID NO 16 is not claimed.

The claimed proteins need only comprise “an amino acid sequence of SEQ ID NO 16” and what the overall sequence of the claimed protein is not so described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. None of these sequences that only comprise an amino acid subsequence of SEQ ID NO 16 meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of

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the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only an isolated polypeptide of SEQ ID NO: 16 and fusion proteins thereof but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶.1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Objections

11. Claim 47 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 45 requires the amino acid sequence to a at least 100 amino

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acid in length, while the polypeptide of claim 47 may be any size amino acid sequence taken from the full length of SEQ ID NO 16. This objection could be obviated by amending the claim to recite ----to the full length of SEQ ID NO 16----.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 24, 45 and 47 rejected under 35 U.S.C. 102(e) as being anticipated Taylor and Ge, (PG-Pub 2002/0068347 now US 6,534,298.)

14. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

15. Ge and Taylor disclose an *Helicobacter pylori* fucosyltransferase that shares 95% identity to a region of 115 amino acids (amino acid 1-115), with only 5 differences in amino acid sequence over the first 115 amino acids (see sequence alignment provided) and has greater than

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95 % identity to the full length of an amino acid sequence of SEQ ID NO 16, (see multiple regions with 100% identity over the full length of SEQ ID NO 16 aligned with the amino acid sequence disclosed by Ge and Taylor. The reference anticipates the instantly claimed invention as now claimed.

16. Claims 24, 45 and 47 rejected under 35 U.S.C. 102(b) as being anticipated Taylor and Ge, (WO98/55630, publication date December 10, 1998).

17. Ge and Taylor disclose an *Helicobacter pylori* fucosyltransferase that shares 95% identity to a region of 115 amino acids (amino acid 1-115), with only 5 differences in amino acid sequence over the first 115 amino acids (see sequence alignment provided) and has greater than 95 % identity to the full length of an amino acid sequence (subsequence) of SEQ ID NO 16, (see multiple regions with 100% identity over the full length of SEQ ID NO 16 aligned with the amino acid sequence disclosed by Ge and Taylor. The reference anticipates the instantly claimed invention as now claimed.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
February 1, 2007



MARK NAVARRO
PRIMARY EXAMINER